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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LAMBERTSON, DAVID A

ART UNIT

PAPER NUMBER

1636

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DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/993,192

Applicant(s)

RHEE ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-20 is/are pending in the application.
- 4a) Of the above claim(s) 18-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/674,617.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

The examiner acknowledges applicant's indication that this is a divisional application, and that claims 1-16 and 21-43 had previously cancelled. At the time of the restriction, there were conflicting amendments in the specification: one indicating that claims 1-16 and 21-43 had been cancelled (dated November 14, 2001, signed by Ms. Diane Dunn McKay), and one indicating that all claims were still pending (dated February 11, 2002, signed by Mr. Brian L. Buckwalter). Because the later-filed amendment did not indicate that the claims were cancelled, the examiner wanted to be sure that applicant was given the appropriate chance to respond to a restriction of all of the claims indicated as pending at the time of the restriction requirement, hence all of the original claims were included in the restriction requirement. Since applicant has confirmed in the response to the restriction requirement that claims 1-16 and 21-43 were indeed cancelled as indicated in the November 14, 2001 amendment, the claims will be treated as such in this and future Office Actions.

Applicant's election with traverse of Group VII (claim 17) in Paper No. 11 is acknowledged. The traversal is on the ground(s) that:

1. A single search is required to evaluate the novelty of the claimed inventions as recited in claims 17-20, because the subject matter of claims 17-20 is the *KEX1* gene. Applicant recites MPEP §803.04, presumably in support of keeping the intact *KEX1* gene and *KEX1* deletion constructs together as simultaneously searchable nucleic acid sequences.
2. Claim 20 is a product-by-process claim which relates to the subject matter of claim 19.

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This is not found persuasive because of the following reasons:

1. The subject matter of each of claims 17-20 is not simply the *KEXI* gene. While claim 17 is drawn to the *KEXI* gene, claims 18 and 19 are drawn to a construct that is designed to delete the *KEXI* gene, thus it comprises a quite different nucleic acid sequence. In this instance, a completely different sequence and non-patent literature search would be required for each claim because neither the *KEXI* gene nor the deletion construct anticipates the other or makes the other obvious. Prior art reading on the *KEXI* sequence would not necessarily produce prior art regarding the deletion construct. Had this vector read on a vector/construct for expressing the full length *KEXI* gene, and then it would be related to the *KEXI* gene. This applies to claim 19 in the same sense, because claim 19 relates to a host cell in which the *KEXI* gene has been deleted, as opposed to a host cell where the *KEXI* gene is expressed. Again, it is the latter of this group that would be related to the *KEXI* gene. Finally, claim 20 is directed to a method of making a protein using a strain in which the *KEXI* gene has been deleted, not a host cell in which the *KEXI* gene is expressed, which would be related to the *KEXI* gene. Thus, while claims 18, 19 and 20 are related to a deletion construct for the *KEXI* gene, they are diametrically opposed to the intact *KEXI* gene, and would require a separate and burdensome search. As it regards the recitation of MPEP § 803.04, applicant is informed that the Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of sequences to be claimed in a single application. Under this policy, a single (1) independent and distinct sequence will be examined in a single application. Thus, searching the *KEXI* deletion construct and the intact *KEXI* gene represents two different sequence searches, which are permissibly restricted.

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2. Claim 20 is a method claim, not a product claim, and therefore cannot be a “product-by-process” claim. As such, it is unclear what applicant is arguing.

The requirement is still deemed proper and is therefore made FINAL.

Claims 17-20 are pending in the instant application. Claims 18-20 have been withdrawn as being drawn to a non-elected invention. Claim 17 is ready for examination in the instant application, and an Office Action on the merits with regard to this claim is provided below.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

If applicant desires priority under 35 U.S.C. 120 based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression “now Patent No. _____” should follow the filing date of the parent application. If a parent application has become abandoned, the expression “now abandoned” should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

In addition, applicant must indicate in the first line of the specification whether an international application to which priority is claimed was published in English under PCT Article 21(2) in English.

Applicant has not satisfied the requirements for a proper priority claim because a priority claim to US Application 09/674,617 is not present either in the first line of the specification or in an application data sheet (ADS). Therefore, priority is granted for this application only so far as it regards the filing date of the application, November 14, 2001.

Information Disclosure Statement

The information disclosure statement filed August 26, 2002, as Paper No. 8 has been considered, and a signed and initialed copy of the form PTO-1449 has been attached to this Office Action.

Specification

It is noted that applicant has submitted a request to transfer the computer readable format (CRF) of the sequence listing of US Application No. 09/674,615 into the instant application (a copy of this requested is submitted for applicant's reference). Applicant is informed that there is no CRF in US Application No. 09/674,615. Therefore, the instant application does not meet the requirements of the sequence rules. However, the examiner noted that applicant intended to claim priority to US Application No. 09/674,617, and determined that the CRF in that application corresponded to the CRF in the instant application. As such, the examiner requested

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that the 09/674,617 CRF be transferred into the instant application in the interest of compact prosecution. However, it is necessary that applicant formally request this transfer to make the record complete. In addition, applicant must supply a statement indicating that the CRF and paper copies are the same and contain no new matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a *KEX1* gene derived from a sequence identified as SEQ ID NO: 3. The claims read on a broad genus of sequences that may or may not represent a *KEX1* gene.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics sufficient to show applicants were in possession of the claimed genus. In the instant case, the specification does not

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sufficiently describe a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics.

Applicant claims a *Hansenula polymorpha KEX1* gene without any disclosed or known indication of the boundaries of the *KEX1* gene, whether or not this particular sequence is a genomic DNA or cDNA molecule, or what represents a *KEX1* gene (is it just the coding sequence, does it include introns, etc.). The specification only provides a ~3500 nucleotide long sequence, and claims that a *KEX1* gene can be derived from this sequence. The specification does not teach what the open reading frame of the *KEX1* gene is or provide a translation of the *KEX1* gene as present in SEQ ID NO: 3, does not indicate how many codons are present in the *KEX1* gene, does not teach where the *KEX1* gene begins and ends with respect to SEQ ID NO: 3, and does not indicate a procedure for how one would derive a *KEX1* gene from this sequence (i.e., what must be done to the sequence in order to make it a *KEX1* gene). The skilled artisan cannot envision any embodiments of the instant invention from the instant specification because the specification does not disclose the nature of the *KEX1* gene relative to the reference sequence. As such, the *KEX1* gene is not described in the instant specification

The prior art does not provide sufficient information on the subject to overcome the deficiencies of the instant specification. There is no description in the prior art that allows one to envision a *Hansenula polymorpha KEX1* gene by disclosing structural or functional features of the gene so that one of skill in the art could envision the claimed invention. Thus the skilled artisan cannot rely on the prior art to envision a sufficient number of embodiments of the instant invention to see that the applicant was in possession of the claimed genus.

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Neither the specification of the instant application or the prior art teaches a structure-function relationship for a *KEXI* gene. As a result, the skilled artisan would not be able to envision the claimed invention by relying on the teachings of the prior art or the instant specification. Therefore applicant has not satisfied the written description requirement to show the skilled artisan that they were in possession of the claimed genus.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is rejected for being indefinite as it concerns the term “derived.” The term “derived” is not defined in either the specification or the instant claim. It is unclear what process can or must be employed in order to “derive” a *KEXI* gene. As it is unclear what must be done in order to “derive” a *KEXI* gene, the metes and bounds of the claim are not defined, and the claim is indefinite.

Claim 17 is rejected for being indefinite as it concerns the term “*KEXI* gene.” The term “*KEXI* gene” is not defined in either the instant specification or the instant claim so as to clearly set forth what is meant by the term. Although it is clear that the *KEXI* gene encodes a carboxypeptidase α protein, it is unclear what the coding sequence is for this gene, especially in the particular organism *H. polymorpha*. Because the *KEXI* gene is not clearly defined (e.g., the coding sequence, associated regulatory regions, non-coding regions, etc.), the metes and bounds

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of the claim are not defined because anything can be called a carboxypeptidase α protein when applicant can be their own lexicographer.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 17 is rejected under 35 U.S.C. 102(b) as being anticipated by Rhee et al. (WO 00/52133; see entire document; henceforth Rhee).

Rhee teaches the cloning of a *KEX1* gene fragment from *Hansenula polymorpha* strain DL1 (see for example page 10, lines 1-13). Although it is also unclear what the amino acid sequence is for this particular *KEX1* gene, the nucleotide sequence from which this *KEX1* gene is derived in this application (also referred to as SEQ ID NO: 3) is identical to that of SEQ ID NO: 3 in the instant application. Therefore, the *KEX1* gene as taught by Rhee must necessarily be identical to that of the instant invention because the sequences from which they are derived are identical.

Allowable Subject Matter

No claims are allowable.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
August 7, 2003

Seward B. Luff, Jr.
PATENT EXAMINER
Gerald B. Letters Jr.
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